

A Framework for Fibromyalgia Management for Primary Care Providers

Lesley M. Arnold, MD; Daniel J. Clauw, MD; L. Jean Dunegan, MD, JD;
and Dennis C. Turk, PhD; for the FibroCollaborative

Abstract

Fibromyalgia is a chronic widespread pain disorder commonly associated with comorbid symptoms, including fatigue and nonrestorative sleep. As in the management of other chronic medical disorders, the approach for fibromyalgia management follows core principles of comprehensive assessment, education, goal setting, multimodal treatment including pharmacological (eg, pregabalin, duloxetine, milnacipran) and nonpharmacological therapies (eg, physical activity, behavioral therapy, sleep hygiene, education), and regular education and monitoring of treatment response and progress. Based on these core management principles, this review presents a framework for primary care providers through which they can develop a patient-centered treatment program for patients with fibromyalgia. This proactive and systematic treatment approach encourages ongoing education and patient self-management and is designed for use in the primary care setting.

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See end of article for correct answers to questions.

From the Department of Psychiatry and Behavioral Neuroscience and the Women's Health Research Program, University of Cincinnati College of Medicine, Cincinnati, OH (L.M.A.); Chronic Pain and Fatigue Research Center, Department of Anesthesiology, University of Michigan, Ann Arbor (D.J.C.); Hillsdale Community Health Center, Brighton, MI (L.J.D.); and Center for Pain Research on Impact, Measurement, and Effectiveness (C-PRIME), University of Washington, Seattle (D.C.T.). A list of additional members of the FibroCollaborative is provided at the end of the article.

Fibromyalgia is a chronic widespread pain disorder estimated to affect 2% to 5% of the US adult population and 0.5% to 5% of other Western populations.¹⁻⁴ In addition to widespread pain present for more than 3 months, patients with fibromyalgia often report fatigue, nonrestorative sleep, cognitive dysfunction, stiffness, and mood disturbance.⁵⁻⁷ With growing recognition of fibromyalgia by patients and health care professionals, more people are seeking medical help for chronic pain conditions and making frequent visits to their health care practitioner.⁸ This has resulted in fibromyalgia becoming a clinical problem commonly seen in primary care and an economic burden on health care resources.^{9,10}

The management of patients with fibromyalgia in the primary care setting may be challenging for several reasons. Although there is increasing evidence about the underlying pathophysiologic mechanisms involved in fibromyalgia,^{11,12} clinicians may find it difficult to communicate this emerging information to their patients. Also, many clinicians report difficulty in identifying and diagnosing fibromyalgia.^{7,13} Finally, patients with fibromyalgia are sometimes perceived as difficult to treat,¹⁴ especially in the primary care office where time and resources may be limited for complex presenting problems. This review is the third and final installment of a series of concise reviews that addresses challenges in fibromyalgia diagnosis, treatment, and management. The series was developed by the FibroCollaborative, an initiative organized and funded by Pfizer in which a diverse group of experts on fibromyalgia provided state-of-the-art information on the understanding, assessment, and treatment of fibromyalgia. Clauw et al¹² presented an

update on pathophysiologic mechanisms in fibromyalgia. Arnold et al⁷ described an approach to the differential diagnosis of fibromyalgia in primary care. This final review provides a framework for primary care providers (PCPs) to treat patients with fibromyalgia effectively as part of a multidisciplinary approach with the goal of improving patient education, symptom management, health status, and outcomes. The framework is similar to the integrated approach taken in the long-term care of other chronic health conditions, such as diabetes, asthma, and hypertension.

A FRAMEWORK FOR THE MANAGEMENT OF PATIENTS WITH FIBROMYALGIA

Educate Patients and Explain Fibromyalgia

As in other chronic conditions requiring ongoing management, education plays an essential role in fibromyalgia management¹⁵⁻¹⁷ and can be integrated into a treatment plan after diagnosis and continued throughout follow-up. Confirming the diagnosis and describing its clinical picture can itself have a positive impact on patients with fibromyalgia, in particular giving them validation and reassurance.¹⁸ For some patients, this alone may improve satisfaction with health status.¹⁹ Furthermore, when the PCP explains fibromyalgia, patients may feel reassured that their symptoms have a cause.¹⁸ When a diagnosis is given, an overview of fibromyalgia's pathophysiology, symptoms, treatment, and prognosis should be provided to aid understanding, acceptance, and self-management. The following examples of common patient questions and possible responses use terms that are understandable to the patient.

What is fibromyalgia?

- Evidence suggests that fibromyalgia is a medical condition in which there are changes in how the central nervous system processes pain. Research shows that changes in the central nervous system cause the brain to process pain signals abnormally in fibromyalgia, leading to pain becoming amplified. It is as if the “volume control setting” for pain is abnormally high. In other words, a person with fibromyalgia has a low pain threshold and may experience pain with a lower stimulus.
- Many of these central nervous system changes also influence sleep, mood, and energy. This helps explain some of the other common symptoms.

What causes fibromyalgia?

- The exact causes of fibromyalgia are not fully understood.
- Evidence suggests that genetic and environmental factors may predispose individuals to development of fibromyalgia.

Can fibromyalgia be cured?

- Fibromyalgia is similar to other chronic conditions in that it cannot be cured, but symptoms can be controlled.
- New treatments are available, and much can be done to improve symptoms and function to enable individuals to get back to doing more of the things that they enjoy and that are important to them.

How is fibromyalgia treated?

- No single treatment works for every symptom.
- Fibromyalgia is usually treated using a combination of approaches, including medications, physical activity/exercise, sleep hygiene, and cognitive behavioral therapy (CBT).
- Treatment requires patients to be active participants in their care.

Time for patient education is often restricted in busy practices, making it important to plan and make optimal use of existing resources. Examples of educational sources in books, on the Internet, and in the community include *Managing Pain Before It Manages You* by Caudill (third edition, 2009); *The Fibromyalgia Help Book* by Fransen and Russell (1996); *The Pain Survival Guide* by Turk and Winter (2006); industry-sponsored websites (eg, www.knowfibro.com, www.fibrocenter.com, www.fibrotogether.com); and patient advocacy organizations (www.painfoundation.org, www.healthywomen.org, www.fmcpcare.org).

Organizing small group lectures for individuals with fibromyalgia and their family members and us-

ing clinical support staff to provide supplemental education are also efficient ways to provide fibromyalgia information.^{16,17} Education should include management of expectations early in the course of therapy. Setting basic expectations for how the clinician and patient will work together can help to establish a productive and efficient partnership and minimize frustration.²⁰ It can be helpful to discuss the following:

- *How frequent office visits will be.* Early in treatment, it may be useful to see patients with fibromyalgia more often and to initiate nonpharmacological therapies in addition to medications to emphasize the important role of multimodal treatment. More frequent visits help clinicians manage early adverse effects of treatment and may improve patients' engagement in all therapies.
- *How much time is available at each visit.*
- *How to prioritize treatment goals.* It is important to discuss the need to take a step-by-step approach rather than trying to solve everything at once.
- *The expected outcomes from treatment and the long-term prognosis of fibromyalgia.* It can be helpful to inform patients of the limitations of treatments as well as potential benefits. For example, medications will help to reduce symptoms but may not eliminate them altogether. However, a reduction in symptoms may allow the patient to engage in nonpharmacological treatments, such as exercise.

Set Treatment Goals

Fibromyalgia, like other chronic conditions, significantly affects multiple domains of a patient's life, including the ability to engage in everyday activities and work.^{5,6} It is therefore important to assess the impact of fibromyalgia across multiple domains at diagnosis and then to work collaboratively in a patient-centered approach during follow-up sessions to develop and prioritize treatment goals with a focus on the domains most affected. A number of questionnaires and assessment tools have been developed and validated to assess pain, patient function (physical, emotional, cognitive, social), and health-related quality of life associated with fibromyalgia.²¹⁻²⁶ Using assessment tools in goal setting at diagnosis gives a “baseline” health status from which progress can be tracked.

Tools made specifically for fibromyalgia include the Fibromyalgia Impact Questionnaire (FIQ)²¹ and the more recently revised version (FIQR).²⁴ The FIQR assesses 3 domains (function, overall impact, symptoms) using 21 check-box questions, and it can be completed in less than 2 minutes.²⁴ Also based on the FIQ, the mVASFIQ assesses 5 symptom domains using 7 scale questions designed for symptom quantification and pharmacological man-

agement, combining visual analog scale scores based on FIQ domains.²⁵

Although yet to be validated to track fibromyalgia progress over time, the 2010 American College of Rheumatology diagnostic criteria²⁶ use symptom severity scores and the widespread pain index to provide numerical scores that can be tracked over time. Individual clinicians can develop other scales based on numerical rating scales or visual analog scale (0-10 cm or 0-100 mm)^{22,23} to provide simple and quick means of assessing symptoms. These scales are adaptable to different domains (eg, pain, sleep quality, mood) and can provide a distinct, comparable score to track symptoms. It is also important for patients to focus on achievable goals related to improved *function*, in addition to change in individual symptoms, such as pain.

The key to effective patient management is for PCPs to research, select, and use the most appropriate tools for each patient and to provide a clear overview of what the results mean for the patient and his or her long-term fibromyalgia management. A patient-centered management plan with prioritized treatment goals should be developed on the basis of these assessments. Importantly, goals should be specific, realistic, and measurable and should reflect patients' priorities.²⁷ Establishing these treatment goals early will help to give structure for follow-up visits, enabling goals to be achieved and progress to be tracked.

Apply a Multimodal Treatment Approach

Because widespread pain and tenderness, along with associated symptoms such as fatigue, sleep disturbance, cognitive difficulties, and mood disturbances, are characteristics of fibromyalgia,^{26,28} no single treatment targets all symptoms. Accordingly, a comprehensive multimodal treatment plan is recommended, integrating (1) ongoing patient education, (2) pharmacotherapy, and (3) nonpharmacological therapies (Figure). Using these principles, the PCP must consider carefully the most appropriate treatment regimen, starting at diagnosis but continuing as the patient's health state changes. Consistent with the treatment approach in other chronic diseases, a number of health care specialists may be required to collaborate on the patient's care, including the patient taking responsibility for self-management and adherence to all aspects of the treatment plan. As for any chronic condition, effective management of fibromyalgia should be viewed through a proactive, patient-centric approach. To achieve this, physicians should *know their patients*, *know their community*, and *know their team* (Figure).

Knowing the patient involves monitoring individuals over the long term for their risk of becoming overwhelmed or unable to engage in the recommended treatment plan. Much of fibromyalgia management depends on what patients do, or do not do,

and what resources are available to help them outside of the PCP's office. Health plan barriers may limit access to nonpharmacological treatments, therapists, or fitness facilities. However, by *knowing their community*, clinicians can highlight alternative options. For example, community resources, such as the YMCA or similar health clubs, may be available for exercise, and Web-based CBT may be an alternative to face-to-face therapist counseling.²⁹ Through *knowing their team*, PCPs are ideally positioned to coordinate care across specialties and to encourage and reinforce the importance of ongoing self-management.

Ongoing Education. Continued education after diagnosis is a key objective of this management framework. As part of this ongoing education, the importance of adherence to all aspects of the treatment program should be highlighted, and nonadherence with pharmacological or nonpharmacological therapies should be addressed, particularly for medications that do not produce an instant, noticeable effect on symptoms. We advise a "start low, go slow" strategy for both pharmacotherapy and any physical exercise program, which should limit adverse events and better assure adherence to any treatment regimen.

Pharmacological Therapies. The US Food and Drug Administration (FDA) has approved 3 medications for fibromyalgia (pregabalin, duloxetine, and milnacipran), which act differently to influence transmission of sensory signals via central nociceptive pathways.³⁰ Approval of these medications contributed to the acceptance of fibromyalgia as a legitimate, treatable condition. As noted earlier in this article, patients and their families should have their expectations managed on initiation of any therapy, with PCPs reiterating that although medications cannot cure the underlying disease, medications can improve symptoms and function.³¹⁻³⁴

Pregabalin is an $\alpha_2\delta$ calcium channel ligand; duloxetine and milnacipran are serotonin and norepinephrine reuptake inhibitors (Table). $\alpha_2\delta$ calcium channel ligands are thought to act in part by reducing the activity of excitatory neurotransmitters (eg, glutamate), whereas serotonin and norepinephrine reuptake inhibitors act largely by increasing norepinephrine and serotonin and thereby increasing activity in the descending inhibitory pain pathways.^{30,35} Efficacy for providing symptomatic benefit to patients with fibromyalgia has been demonstrated in specifically designed studies. Other medications, such as tricyclic medications (eg, amitriptyline, cyclobenzaprine), gabapentin, tramadol, fluoxetine, and sodium oxybate, are also used for symptomatic management and

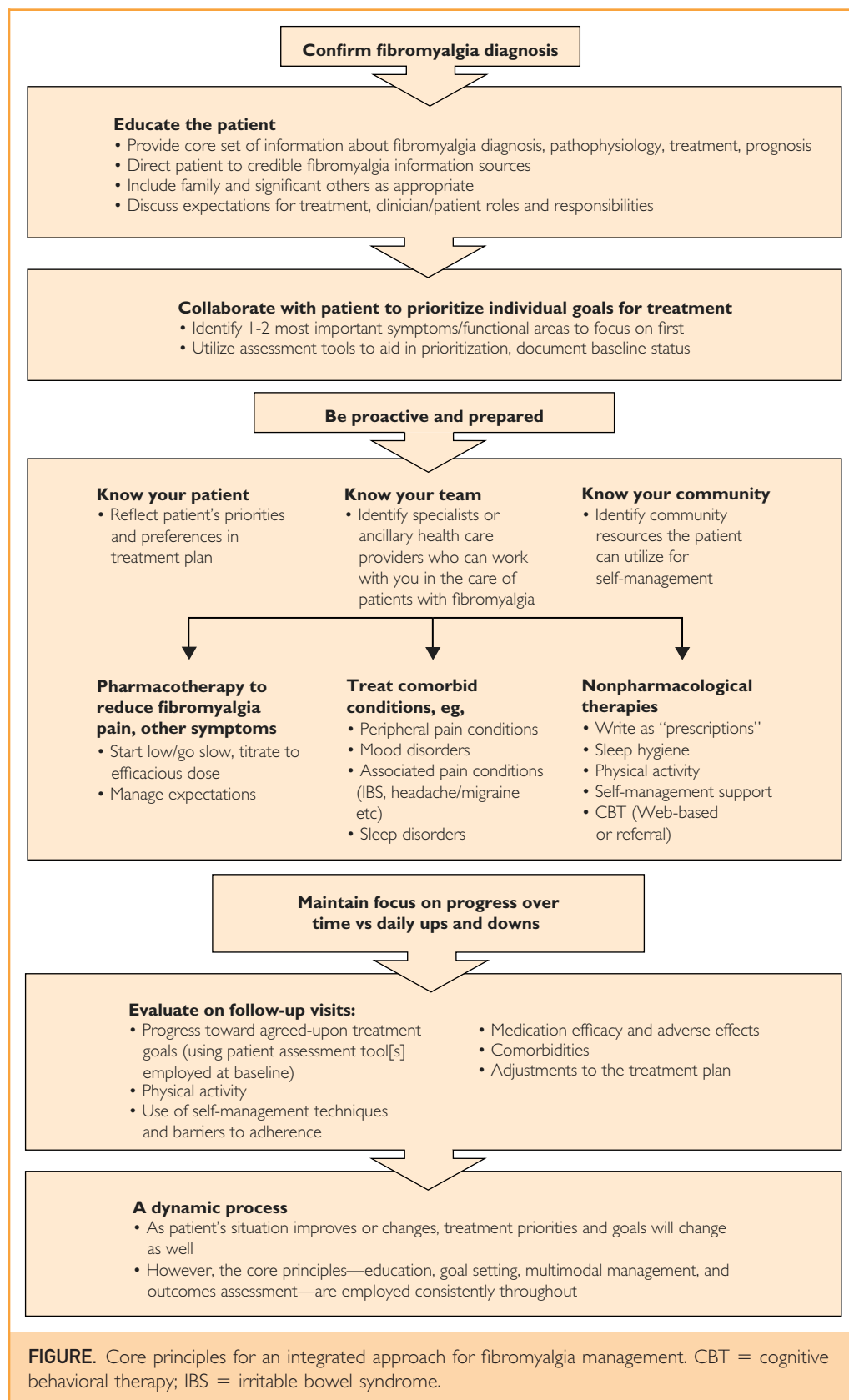


TABLE. Summary of Treatment Regimens for Pharmacological and Nonpharmacological Therapies Used in Multimodal Management of Patients With Fibromyalgia^a

Therapy	Representative treatment regimen	Outcomes ^b
Pharmacotherapy		
Pregabalin (alpha ₂ delta ligand)	Start at 75 mg BID and up-titrate to 300-450 mg/d (150-225 mg twice a day) ^c	<ul style="list-style-type: none"> • Significant reduction in pain (11-point NRS) • Improvement in other subjective ratings of fibromyalgia symptoms (PGIC; FIQ total score) vs placebo³⁴ • Most common AEs^b: dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, abnormal thinking (primarily difficulty with concentration/attention)^c • Discontinuation from clinical trials of fibromyalgia due to AEs: 19% for patients treated with pregabalin (150-600 mg/d) vs 10% for placebo^c • AEs most often leading to discontinuation of pregabalin: dizziness (6%) and somnolence (3%)^c
Duloxetine (SNRI)	Start at 30 mg/d and up-titrate to 60 mg once daily ^d	<ul style="list-style-type: none"> • Significant reduction in pain (BPI and pain interference) • Improvement in other subjective ratings of fibromyalgia symptoms (PGIC; FIQ total score) vs placebo³¹ • Most common AEs^b: nausea, dry mouth, somnolence, fatigue, constipation, decreased appetite, hyperhidrosis^d • Discontinuation from clinical trials of fibromyalgia due to AEs: 18.7% for patients treated with duloxetine (60-120 mg/d) vs 10.8% for placebo^d • AEs most commonly leading to discontinuation of duloxetine: nausea (2.1%), somnolence (1.2%), and fatigue (1.1%)^d
Milnacipran (SNRI)	Start at 12.5 mg/d and up-titrate to 50 mg twice a day ^e	<ul style="list-style-type: none"> • Significant reduction in pain (VAS) and in composite responder rate • Significant improvement in other subjective ratings of fibromyalgia symptoms (PGIC, SF-36 domains; FIQ total score) vs placebo³³ • Most common AEs^b: nausea, headache, constipation, dizziness, insomnia, hot flush, hyperhidrosis, vomiting, palpitations, increased heart rate, dry mouth, hypertension^e • Discontinuation from clinical trials of fibromyalgia due to AEs: 23% and 26% for patients treated with milnacipran (100 and 200 mg/d), respectively, vs 12% for placebo^e • AEs most commonly leading to discontinuation of milnacipran: nausea (6%), palpitations (3%), and headache (2%)^e

(continued)

TABLE. (continued)

Therapy	Representative treatment regimen	Outcomes
Nonpharmacological		
Education	Provide core information about fibromyalgia diagnosis, physiology, treatment, prognosis, importance of exercise, sleep. Manage expectations	<ul style="list-style-type: none"> Varied degrees of improvement in patient symptoms and/or functions through education (often in combination with CBT and/or exercise programs)^{15,17}
Physical activity	Start low, go slow; eg, walk 10 min/d, build to 30-60 min of low or moderate activity up to 2-3 times/wk	<ul style="list-style-type: none"> Improvement in physical function and HRQoL and symptoms of fibromyalgia, including pain, depressed mood, and fatigue⁴⁰
CBT/Web-based CBT	CFIDS and Fibromyalgia Self-Help (www.cfidsselfhelp.org ; www.treatcfsfm.org) Arthritis Foundation's Fibromyalgia Self-Help Course Online self-help courses, tools, books, and CDs Face-to-face CBT counseling	<ul style="list-style-type: none"> Improved knowledge about fibromyalgia and how to cope with pain³⁷ Significant improvement in physical (pain, fatigue, and functional disability) and psychological (negative mood and anxiety) functioning and in impact of fibromyalgia in patients treated with CBT combined with exercise vs no CBT⁴¹ Significantly greater improvement in pain, physical functioning, and overall global improvement reported by patients randomized to standard care plus access to an Internet-enhanced behavioral self-management program designed for use in routine clinical care compared with patients receiving standard care alone²⁹ Improvements often sustained for months after CBT stopped³⁸
Sleep hygiene	Make sleep routine a priority. Optimize relaxing sleep environment. Provide advice on diet and exercise: avoid nighttime stimulants (eg, coffee); exercise during the day; hide clock	<ul style="list-style-type: none"> Improving sleep hygiene can increase favorable outcomes on measures of pain (BPI) and mental well-being (SF-36)³⁹
<p>^a AE = adverse event; BPI = Brief Pain Inventory; CBT = cognitive behavioral therapy; CFIDS = chronic fatigue and immune dysfunction syndrome; FIQ = Fibromyalgia Impact Questionnaire; HRQoL = health-related quality of life; NRS = numerical rating scale; PGIC = Patient Global Impression of Change; SF = short form; SNRI = serotonin and norepinephrine reuptake inhibitor; VAS = visual analog scale.</p> <p>^b Safety is based on the most frequently occurring adverse reactions ($\geq 5\%$ and twice placebo for pregabalin^c and duloxetine^d or $\geq 5\%$ and greater than placebo for milnacipran^e).</p> <p>^c For further detail, see prescribing information: http://labeling.pfizer.com/ShowLabeling.aspx?id=561.</p> <p>^d For further detail, see prescribing information: http://pi.lilly.com/us/cymbalta-pi.pdf.</p> <p>^e For further detail, see prescribing information: http://www.frx.com/pi/Savella_pi.pdf.</p>		

have demonstrated efficacy in randomized controlled trials for fibromyalgia (see article by Arnold³⁶ and references therein). Although none are specifically indicated by the FDA for the management of fibromyalgia, the lower cost of generic products may lead some physicians to prescribe them if patients cannot afford the FDA-approved medications. Patients with fibromyalgia may also use other analgesics, such as nonsteroidal anti-inflammatory agents and opioids, for pain management; however, their efficacy has not been demonstrated in trials of patients with fibromyalgia.³⁶ As part of *knowing their patients*, PCPs should recommend the most appropriate treatments for each individual patient, according to his or her clinical history and presentation. Further detail regarding a stepwise approach to

selecting medications that could be integrated into the fibromyalgia management framework has been published elsewhere.³⁶

Nonpharmacological Therapies. Several nonpharmacological approaches are beneficial to patients with fibromyalgia, reducing pain and improving function (Table). We recommend incorporating appropriate nonpharmacological approaches into the overall treatment plan as written “prescriptions” to highlight their equal importance to medications. Among the nonpharmacological approaches that have demonstrated efficacy in clinical trials are exercise; sleep hygiene; some forms of CBT, including Web-based CBT; and ongoing patient edu-

cation.^{15,17,29,37-41} Furthermore, other nonpharmacological approaches, such as yoga, massage, and other types of physical therapy, may also be considered,⁴² although more study is needed to assess their efficacy in fibromyalgia. An integrated approach is key, and the importance of self-management should be highlighted. For example, the benefits of exercise were enhanced in one study when exercise was combined with a targeted self-management program (the Arthritis Foundation's Fibromyalgia Self-Help Course).¹⁷ Providing materials that promote basic self-management techniques to accomplish daily activities and manage symptoms, in addition to suggesting ways to incorporate wellness activities into daily life, should form the foundation of guided self-management. Family members and significant others should be actively involved from the outset, particularly when symptoms of fibromyalgia have placed a strain on these relationships. In fact, integrating family members into the treatment program may aid effectiveness.⁴³ It is also important for PCPs themselves to ensure that they are sufficiently knowledgeable about these nonpharmacological practices to give their patients succinct advice and recommendations for self-management. This is particularly needed for treatments such as CBT, a term often used in the lay press to encompass a wide range of disparate approaches to therapy. The key ingredients in CBT are problem solving, stress management, and self-control.

Inadequate sleep is a common and problematic symptom of fibromyalgia, and sleep hygiene is an area of growing interest. Indeed, disrupting slow-wave sleep for consecutive nights is associated with decreased pain threshold, increased musculoskeletal pain, and fatigue,⁴⁴ suggesting an interrelationship between sleep and pain. Behavioral strategies aimed at improving sleep hygiene (some are outlined in the Table) can help individuals improve sleep quality and, if used regularly, may lead to additional benefits, such as improved mood and mental clarity, less fatigue, and less pain.³⁹ Primary care providers should also consider the possibility of a comorbid sleep disorder and referral to specialists in the evaluation of sleep problems.⁷ Collaboration with other clinicians in the evaluation and treatment of patients with fibromyalgia is part of PCPs' *knowing their team*.

Track Progress

The course of fibromyalgia is not straightforward, with pain and symptoms fluctuating over time.⁴⁵ Given the complexity and chronic nature of fibromyalgia, and the impact on patients' daily lives, there is a clear need to track progress. Tracking progress will help patients focus on self-management and encourage motivation, particularly after a flare-up or period of poor health. For some chronic

diseases, protocols are provided that identify variables to track over time. Currently no such protocols exist for fibromyalgia. However, several questionnaires and assessment tools are available (discussed earlier in this article) that can and should be selectively employed to track patient progress.

CONCLUSION

Many complex chronic diseases are effectively managed in primary care, supported by collaboration with health care specialists in a patient-centered approach. Management of patients with fibromyalgia in the primary care setting should be approached in a similar manner, by implementation of a chronic care framework based on core principles of education, goal setting, multidisciplinary management, routine monitoring, and outcomes assessment (focusing on improvement in symptoms, physical and emotional functioning, and overall health-related quality of life). Follow-up should involve specific resources that help health care professionals educate patients and their families to engage in self-management and carry out ongoing assessment to track disease status over time. Because no single treatment approach for fibromyalgia targets all symptoms or will manage every patient, there is a clear need for a dynamic, multifaceted approach to management. Using these principles, PCPs, in association with other health care professionals and patients themselves, can form an active health care team to enhance well-being and reduce patient suffering.

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Abbreviations and Acronyms: CBT = cognitive behavioral therapy; FIQ = Fibromyalgia Impact Questionnaire; PCP = primary care provider

Additional Members of the FibroCollaborative: Kenneth Barrow, PA-C, MHS, Independence Back Institute, Wilmington, NC; Lucinda Bateman, MD, Fatigue Consultation Clinic Inc, Salt Lake City, UT; Larry Culpepper, MD, MPH, Boston University, Boston, MA; Cassandra Curtis, MD, American Health Network, Greenfield, IN; Yvonne D'Arcy, MS, CRNP, CNS, Suburban Hospital-Johns Hopkins Medicine, Bethesda, MD; Kevin B. Gebke, MD, Indiana University, Indianapolis; Robert Gerwin, MD, Pain and Rehabilitation Medicine, Bethesda, MD; Don L. Goldenberg, MD, Newton-Wellesley Hospital, Newton, MA; James I. Hudson, MD, ScD, McLean Hospital/Harvard Medical School, Belmont, MA; Rakesh Jain, MD, MPH, Clinical Research Center, Lake Jackson, TX, University of Texas Medical School, Houston; Texas Tech School of Medicine, Midland; Arnold L. Katz, MD, Overland Park Regional Medical Cen-

ter, Overland Park, KS; Andrew G. Kowal, MD, Tufts University, Burlington, MA; Charles Lapp, MD, Duke University, Charlotte, NC; Michael McNett, MD, The Paragon Clinic for Fibromyalgia & Muscular Pain, Chicago, IL; Philip J. Mease, MD, Swedish Medical Center, Seattle, WA; Danielle Petersel, MD, Pfizer Inc, New York, NY; I. Jon Russell, MD, PhD, University of Texas, San Antonio; Stephen M. Stahl, MD, PhD, University of California, San Diego; Roland Staud, MD, UF Center for Musculoskeletal Pain Research, University of Florida, Gainesville; Alvin F. Wells, MD, PhD, Rheumatology & Immunotherapy Center, Oak Creek, WI.

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Correspondence: Address to Lesley M. Arnold, MD, Professor of Psychiatry and Behavioral Neuroscience, Director, Women's Health Research Program, University of Cincinnati College of Medicine, 222 Piedmont Ave, Ste 8200, Cincinnati, OH 45219 (Lesley.Arnold@uc.edu).

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QUESTIONS ABOUT FIBROMYALGIA

1. A framework for managing patients with fibromyalgia consists of all of the following **except**
 - a. Educate patients and explain fibromyalgia
 - b. Emphasize that earlier diagnosis and treatment can lead to a cure
 - c. Set treatment goals and expectations
 - d. Apply a multimodal treatment approach
 - e. Track progress and manage expectations
2. Pharmacological agents approved by the Food and Drug Administration for the management of fibromyalgia include
 - a. Duloxetine, pregabalin, amitriptyline
 - b. Gabapentin, milnacipran, duloxetine
 - c. Pregabalin, duloxetine, cyclobenzaprine
 - d. Venlafaxine, gabapentin, duloxetine
 - e. Pregabalin, duloxetine, milnacipran
3. Nonpharmacological approaches to fibromyalgia management include all of the following **except**
 - a. Education
 - b. Sleep hygiene
 - c. Cognitive behavioral therapy
 - d. Physical activity
 - e. High-intensity aerobics
4. Which assessment tool was specifically developed for use in patients with fibromyalgia?
 - a. Numerical rating scale
 - b. Patient Global Impression of Change
 - c. Visual analog scale
 - d. Revised Fibromyalgia Impact Questionnaire
 - e. Brief Pain Index
5. This framework approach to self-management of fibromyalgia is based on which clinician type as the care coordinator?
 - a. Rheumatologist
 - b. Pain specialist
 - c. Primary care provider
 - d. Psychiatrist
 - e. Neurologist

CORRECT ANSWERS: 1. b. 2. e. 3. e. 4. d. 5. c